

**AMENDMENTS TO THE DRAWINGS:**

The attached sheets of drawings include changes to the images in these drawings to make the images clearer. These changes do not substantively alter the drawings.

Attachments: Replacement Sheets, 8 sheets for Figures 1-8.

## REMARKS

With entry of this Amendment, claims 9-11 and 17-19 are pending. Applicants have canceled claims 7, 8, 12-16, and 20-35 without prejudice or disclaimer and retain the right to prosecute the subject matter of these claims in future applications. Applicants amended claims 9 and 17 into independent form. The amendment to claim 9 is based on claim 7 and the amendment to claim 17 is based on claim 16. Thus, no new matter has been added.

The Office objects to the drawings because Figures 1-8 are allegedly not visible. (Office Action, p. 3.) To expedite prosecution, Applicants attach to this Amendment eight (8) replacement sheets. The images provided on the replacement sheets are the same as those in original Figures 1-8, but of higher quality and clarity. Applicants request that the Office withdraw this objection or notify the undersigned if the attached drawings are not acceptable.

The Office rejects claims 7-22 under one or more of 35 U.S.C. §§ 112, 102, and 103. Applicants address these rejections with regard to pending claims 9-11 and 17-19.

### Rejection Under 35 U.S.C. § 112

Claims 7-22 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. (Office Action, p. 4.) Because this rejection addresses "claim 7 and its dependent claims," Applicants assume that the Office applies this rejection to claims 7-15. Claims 16-22 are not dependent on claim 7. According to the Office, claim 7 is indefinite because it is not clear what the phrase "caused by at least one of a virus and a bacterium" refers to. (*Id.*) Applicants address this rejection with respect to claims 9-11, which are still pending. The phrase referred to by the Office acknowledges that in some embodiments of claim 9, a subject's infection can be caused by more than one

virus in the case of, for example, a superinfection. Likewise, an infection can be caused by one or more bacterium or caused by a combination of viruses and bacteria in the subject. Thus, the phrase “caused by at least one of a virus and a bacterium” is meant to address all of these possible embodiments. Applicants request that the Office withdraw this rejection in light of this explanation.

#### Rejection Under 35 U.S.C. § 102

The Office rejects claims 7, 8, 13, 14, 16, 21, and 22 under 35 U.S.C. § 102(b) as allegedly anticipated by Caliezi et al., *Pharm. Rev.* 52:91-112 (2000) (“*Caliezi*”). (Office Action, p. 4.) According to the Office, *Caliezi* teaches a method of treating septic shock caused by an acute infection by *E. coli* or *S. typhimurium* comprising administering C1 esterase inhibitor (C1-INH) intravenously. (*Id.* at p. 5.) Acknowledging that *Caliezi* does not teach that *E. coli* or *S. typhimurium* comprise hemagglutinin or neuraminidase, the Office suggests that *E. coli* inherently expresses hemagglutinin. (*Id.*) In addition, because of the alleged anti-inflammatory activity of C1-INH, the Office concludes that administration of C1-INH to a subject would inherently modulate the immune response. (*Id.*)

In the interests of advancing prosecution and without acquiescing in the rejection, Applicants have canceled claims 7, 8, 13, 14, 16, 21, and 22. Because the Office’s rejection is now moot, Applicants request that the Office withdraw it.

#### Rejections Under 35 U.S.C. § 103

The Office rejects claims 12 and 20 under 35 U.S.C. § 103(a) as allegedly obvious over *Caliezi* in view of Newman et al., *J. Amer. Acad. Derm.* 29:909-12 (1993) (“*Newman*”). According to the Office, claims 12 and 20 are drawn to the limitation of the

bacterium being *V. cholerae*. (Office Action, p. 7.) The Office applies *Caliezi* as discussed above and notes that this reference does not teach that *V. cholerae* causes sepsis. Turning to *Newman*, the Office attempts to bridge this gap by contending that *Newman* teaches that *V. cholerae* causes sepsis. (*Id.*) The Office concludes that it would have been obvious to use the method of *Caliezi* on a patient with sepsis caused by *V. cholerae* because *E. coli* and *S. typhimurium* (discussed in *Caliezi*) and *V. cholerae* (discussed in *Newman*) cause sepsis and C1-INH can be a treatment for sepsis. (*Id.*) The skilled artisan would allegedly have a reasonable expectation of success because C1-INH works as an anti-inflammatory agent against inflammation caused by endotoxins. (*Id.* at pp. 7 and 8.)

In the interests of advancing prosecution and without acquiescing in the rejection, Applicants have canceled claims 12 and 20. Because the Office's rejection is now moot, Applicants request that the Office withdraw it.

Claim 15 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over *Caliezi* in view of *Gustafson* (U.S. Patent 7,014,857) ("*Gustafson*"). Applying *Caliezi* as discussed above, the Office acknowledges that *Caliezi* does not teach administering a vaccine against the bacterium. (Office Action, p. 8.) The Office refers to *Gustafson* for the alleged teaching of a vaccine to treat sepsis caused by *E. coli*. (*Id.*) It would have been obvious, the Office contends, to combine the C1-INH of *Caliezi* with the vaccine against bacteria causing sepsis because both C1-INH and the vaccine are used to treat sepsis caused by bacterial infection. (*Id.*) Citing M.P.E.P. § 2144.06, the Office asserts that it is *prima facie* obvious to combine two compositions, each of which are taught to be useful for the same purpose, in order to form a third composition. (*Id.*)

In the interests of advancing prosecution and without acquiescing in the rejection, Applicants have canceled claim 15. Because the Office's rejection is now moot, Applicants request that the Office withdraw it.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of pending claims 9-11 and 17-19.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: March 28, 2007

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**Attachments:** Replacement Sheets, 8 sheets for Figures 1-8.